Report to ONC Adoption / Certification Workgroup
Panel on HIT Safety

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Preamble

Health care is information-intensive. The introduction of information technology into the practice of health care has had, and will continue to have a profound effect on the way health care is practiced. As with other health care technologies (for example, medications and surgery), information technology can greatly improve the quality, safety and efficiency of care, and may have adverse consequences as well. Efforts that help to assure that the beneficial effects of IT are realized while the risks are minimized are to be applauded.

These comments are based on my involvement with clinical information systems at 3 large health care provider organizations (Intermountain Health Care, Partners HealthCare System and NewYork-Presbyterian Hospital), comments from topics that have been discussed on the Clinical Information Systems Working Group of the American Medical Informatics Association (AMIA), which I chaired for 4 years, and from the American Directors of Medical Information Systems (AMDIS) list serve, an active and frank forum for issues related to the positive and negative consequences of health information technology.

In these remarks, I have defined "safety" as "freedom from injury, and I have considered circumstances that have a reasonable likelihood of leading to a preventable untoward patient event. There are other circumstances that may lead to inefficiencies (which secondarily may lead to an untoward event) but for the most part I have not made those circumstances the focus of these remarks.

Thank you for your efforts and for allowing me to contribute to these deliberations.

1 What are patient-safety risks that may be introduced inadvertently through the use of electronic health records (EHRs) or other HIT products?

Introductory comments

There are several examples of actual or potential adverse events in which information technology can play, at least in part, a causative role. The "Swiss cheese" model points out that a single factor rarely is the antecedent of an adverse event. Paper-based information management, as well as automated information technology may be one of many factors that eventually lead to an undesired outcome. The role of paper may be less recognizable so often is not scrutinized so extensively.

Patient safety risks can occur in one of the following categories:

a) Reviewing patient data
b) Entering orders
c) Documenting notes
d) Communication
e) Clinical decision support
f) IT-workflow integration
g) Miscellaneous

This scheme deliberately focuses on the impact of the HIT on the clinician. The first 4 categories are workflow activities of clinicians that exist even in a paper-based environment. Clinical decision support is an aspect of work that is introduced only with HIT. IT-workflow integration is critical to assure that an appropriate technology is used in an appropriate way. A Miscellaneous category has been added.

The examples that follow of patient safety risks that HIT can introduce into these workflow activities are not intended to be comprehensive. Rather, they are intended to give a sense of the kinds of risks that may be present when information technology is introduced.

a. Risks related to using HIT to review patient data

Introductory note: Clinicians review data to make diagnostic and treatment decisions. Any aspect that hinders complete, accurate and facile access to the patient's data creates a safety risk.

i. Errors in organizing the patient's data so that it is not easily retrieved in a complete, accurate and facile way by clinicians may introduce risk. Even in the best of circumstances, categorizing tests can be complex. For example, it may be unclear whether tests should be organized

under serology or microbiology. Clinicians may miss key results in these circumstances. Miscategorization of specific tests within a results view hierarchy may create risk.

ii. Screen presentations that attempt to organize large amounts of complex data may be confusing or incomplete. Despite well more than 40 years of experience with the development of results viewing applications, the optimal way to display large amounts of patient data still is not completely understood. Patients who have had large numbers of laboratory results or who have large volumes of data in intensive care settings present particular challenges.

iii. HIT applications that oblige the clinician to navigate an unduly complex set of screens to get to the desired data may introduce risk because the clinician who is seeking information may abandon his or her search out of frustration and make a decision with less than complete information.

b. Risks related to entering orders

Introductory note: Decisions made by physicians are often entered as orders. Any aspect of the information system that reduces the fidelity of the physician's intentions at the time the order is entered may create a patient safety risk.

i. In general, poor design of the application may lead a clinician to enter orders with less than absolute certainty that what has been entered is what they had intended. Poor design or configuration also may make it unclear when an order has been committed and so double entry of an order or the mistaken impression that an order has been entered (when in fact it has not) may occur.

ii. Entering orders on the wrong patient. This can occur if the physician is distracted and / or if the patient's identifying information is not clearly presented.

iii. Picking the wrong kind of order (e.g., measles serology vs. measles vaccine) if orderable options have been configured ambiguously.

iv. Errors in creating complex orders with multiple parameters, such as fluids with multiple additives or TPN orders. Such orders may need to be constructed in a variety of ways, e.g., a fixed amount of additive per unit time, a fixed amount of additive per unit volume, etc. The complexity may result in an order that was different from what the ordering physician intended.

v. Entering field level data in a way that was not intended, for example

1. Juxtaposition errors – picking the wrong item in a list

2. Misusing a multi-select list box (not realizing that the default item is automatically part of the resultant list)

vi. Errors in orders at the time of patient transfer. For example, not all medications may be discontinued or restarted, other orders (e.g., diets, patient mobility, etc.) may not be communicated accurately.

c. Risks related to documenting the patient encounter

Introductory note: A safety risk is created if the clinician's assessment of the patient's state either is not entered accurately or is not easily understood by other members of the care team.

i. Electronic documentation features that encourage verbose summaries that are not reviewed by other members of the care team.

ii. Risks related to fragmentation of the record across multiple electronic systems or across electronic and paper based systems.

d. Risks related to communication

Introductory note: Communication is a critical component of care that is supported by information technology (indeed, the term "ICT", for "information and communication technology" is often used in place of "IT"). Examples of critical communication include: physician to nurse, nurse to pharmacist, primary care physician to specialist, transferring physician to receiving physician, laboratory to physician, etc. The clinical information system may be an explicit or implicit communication intermediary. Misunderstanding or misuse of the communications aspects of the HIT may create a safety risk. The communication aspects of HIT are critical because with the ability to enter orders and notes remotely, there may be less face-to-face interaction of the members of the care team.

i. Entering data into an alert comment field (e.g., "do not give these 2 interacting drugs simultaneously") thinking that a nurse would be reviewing the comment when in fact the comment field was intended to be used to comment on the alert.

ii. Inadequate follow up because results that become available post-discharge are not communicated effectively to a provider who can act on those results.

iii. Data entry fields that (unbeknownst to a provider) are truncated when they are communicated to another provider or an ancillary system.

e. Risks related to clinical decision support

Introductory notes: Electronic clinical decision support is an aspect of care that does not have a direct analog in the paper world. This is the ability of the computer system to actively present information to a member of the care team regarding a potential action that has not yet occurred or critique or comment on an action that has occurred. The specific clinician that is the

target of the clinical decision support and the method of notification can vary widely.

Clinical decision support functions by making inferences on data. When compared with human experts, the inferences may agree with the expert or may disagree; disagreements may be false positives or false negatives. Patient safety risks can occur from either false positives or false negatives. No clinical decision support system has perfect discriminatory performance characteristics. The optimal levels of false positive and false negative rates are not known. "Alert fatigue", defined as an excessive production of false negative alerts has been well described. Another kind of fatigue may occur when the number of appropriate alerts exceeds the clinicians capacity to process the alerts. In this case, decisions need to be made about which alerts have the highest "value".

Some examples of patient safety risks related to clinical decision support are:

i. Computer-based logic may be incomplete. For example, a rule may be written that says "If the patient has had a myocardial infarction and the patient is not receiving aspirin, recommend aspirin". The rule may not take into account whether the patient is receiving warfarin.
ii. A clinical decision support rule may be ignorant of relevant data that is not accessible, for example, an elevated creatinine at another care facility.
iii. The provider organization may not be able to keep up with evolving knowledge, for example, new dosing recommendations or new interactions. This may be true whether the organization is using vendor-provided knowledge sources or developing its own knowledge sources.
iv. Crafting concise actionable alert messages is an art. Organizations that do not craft such message well may miss the opportunity to influence physician behavior in the most effective way.
v. The effectiveness of clinical decision support may be negatively impacted by changes to foundational aspects of the system. For example, a rule that triggers on the ordering of "heparin" would no longer fire when the organization's medication dictionary is edited to accommodate new formulations of heparin.
vi. Errors in the design of dosing calculators. This may be calculators from vendor-based sources or from internally developed "logic modules".

vii. Incompleteness of specialized dosing knowledge, for example, renal dosing rules, geriatric dosing rules, anticoagulation dosing rules, etc. The rules that are present may be correct but there may be combinations of ages, laboratory results, drugs, etc., that are not covered by the rule base.

f. IT-workflow mismatch

Introductory note: There are instances in which the application is working "as designed", however the human workflow that surrounds the application creates an undesired outcome

i. Orders that are time limited and need to be renewed (e.g., pain medications, certain antibiotics), however the workflow does not support reliable renewal of the orders, either because the "right person" to renew the order is not known, or because there is no way to communicate with the correct individual, or because there is no escalation procedure if the first contact does not respond.

ii. Data that are not entered in real-time because the devices are not proximal to the workspace, e.g., entering medication administration data at the end of the shift rather than in real-time because the workstations are busy or inaccessible. This leads to an inaccurate picture for a clinician or a logic module accessing the database.

iii. Administrative screens that request data not critical to care per se that cause frustration and lead clinicians to enter incomplete or incorrect data.

g. Miscellaneous

i. (Rare, but do occur) Software bugs that lead to odd behavior of system, e.g., system hangs, loss of entered data, etc. Usually, clinician is aware and frustration is the result.

2 Are there specific types of risks that are more common than others?

I am not aware of epidemiologic studies looking at the rates of these kinds of errors and risks. Any of the categories of risks described above certainly could lead to undesired and adverse consequences for patient care. Risks related to orders are especially worrisome because of their proximity to the patient.

Any epidemiologic study would need to take into account the severity of the error, the preventability of the error, and the extent to which the error is germane just to the environment in which it occurred or whether it is relevant to other settings as well.

3 What are the causes of those risks?

The impact of clinical software (whether positive or negative) results from the complex interaction of: (a) the software itself, (b) the task at hand, (c) the work flow into which the execution of the task needs to fit, and (d) a user who is (i) influenced by the amount of training they have had, and (ii) at any point in time may be performing at a varying level of cognitive awareness.

When considering the software itself, it is important to realize that the software likely has been (i) developed, (ii) configured, and (iii) implemented by different parties. In complex organizations, the parties that are implementing the software may not be the ones who originally configured the software and so some of the nuances of the software may not be appreciated at the time of implementation and training.

When there is an undesirable outcome from the interaction of the individual with the software, one would have to ask why, and which of these factors, possibly in combination might have played a role. Pure defects in the software that was provided by the vendor are a rare cause of these events. Certainly, such defects, when they are identified, should be fixed as soon as possible. However, an undue focus on pure software defects may distract us from some of the other, perhaps more relevant factors that are suitable targets for improvement.

The interaction of HIT with provider organizations' policies may introduce risk. For example, at the time of patient transfer, in some instances (e.g., a transfer to the ICU) it may be the receiving provider who is responsible for reconciling the final orders; in other circumstances (e.g., transfer from the recovery room to the acute care ward), it may be the transferring provider who is responsible. The software may be optimized to best support only one of these models causing a risk of transfer-related error.

4 What are ways to prevent and/or mitigate those risks?

In an article in JAMA in September, 2009, Sittig and Singh note that there are 8 "rights" to assure that EHR use is safe: right hardware and software, right content (e.g., decision support, order sets), right user interface, right personnel, right workflow and communication, right organizational characteristics, right state and federal rules and regulations, and right monitoring.

In general, I think this is a helpful framework. I would note that some of the "rights" are prerequisites (hardware/software, organizational characteristics, regulations), and others are outcomes of a successful implementation (workflow, user interface, content, monitoring). Right personnel are critical, but it's not clear whether this should be treated as a prerequisite, i.e., the right personnel should be hired, or as an outcome, i.e., the right personnel should be developed by the organization.

Also, I would note that something is needed to take the organization from the "right" prerequisites to the "right" outcomes. I would suggest that in addition to Sittig and Singh's 8 rights, another right, the "right" implementation approach also is needed.

Much more needs to be learned about the human cognitive experience of using clinical software. The clinical information "space" is very complex. System designers make assumptions when systems are designed (e.g., about which fields the user is aware of when the application is being used). Ideally, processes should be put into place that assures that the designers' assumptions are correct.

More work also is needed on testing. Testing software in general is complicated and testing clinical software is especially complicated. Best practices should be established and encouraged. Testing should be done after configuration. Testing is complicated in health information exchange settings.

5 How would you weigh the benefits and risks of using EHRs in patient care?

There is a paucity of studies that compares the safety of care with and without health information technology. Some studies have shown that physicians receive lab results faster with electronic systems as compared with paper systems. Another study showed an initial increase in ordering errors with computer order entry, which was subsequently addressed.

As mentioned previously, several of the problems that have been associated with EHRs (e.g., difficulty retrieving patient data, unreliable communication, etc.) exist in environments without EHRs but are less explicit. Therefore, the identification of HIT-related errors and adverse events does not mean that care is safer without information technology; only that information technology should continue to be improved. The approach to implementation and assuring that the application is configured correctly and that the application fits the workflow of

the organization should be the foci of improvement. In large organizations, this should be the responsibility of the organization itself; in small practice settings, Regional Extension Centers (RECs) may have a role to play.

My personal opinion is that with the explicitness of data entry, the reliability of data retrieval and the improvements in communications, even the systems we have today are superior to paper-based technologies. I believe that significant improvements to the state of the art of clinical information systems are needed if we are to realize the full potential of these systems to support a modern health care system.

6 How might data on risks best be identified as greater HIT adoption occurs?

Barriers should be reduced to the frank and open communication within health care organizations about the impact of technology on the quality of care. Large health care organizations should be required to have a plan to assure the effective implementation of clinical systems and to obtain feedback about opportunities for improvements. Regional Extension Centers may be able to play this role for small provider organizations.

7 What are the factors that might impact an organization from reporting adverse events or known concerns about HIT products?

Incident reporting, in general, at hospitals is still immature. To what extent a "blame-free" culture should be promulgated to promote incident reporting still is a topic of active debate. Voluntary reporting has limitations in terms of sensitivity. Minor problems often are reported with great frequency, but serious problems may not be reported. An individual reporting an event may not understand clearly to what extent technology played a role, and if so, to what extent the technology was causative.

James Walker from Geisinger has described a systematic approach to collecting data about potential hazards related to the use of health information technology that has been in use at Geisinger Health System for several years. This system has been expanded and is in a beta testing phase to see how it functions at other organizations around the country. If something like the hazard risk manager is successful and becomes widespread, that could affect the approach to collecting and disseminating information about problems with health information

technology. Progress on the hazard risk manager should be watched with great interest.

Provider organizations should be encouraged to develop policies and procedures that demonstrate they are taking appropriate steps to minimize risks of improper outcomes from the use of the system. This includes policies related to training, testing, and configuration.

Health care organizations should be encouraged to have proper processes and procedures for installing clinical information systems. For example, proper processes for configuration, training, implementation, development of order sets and alerts, etc. Ideally, organizations would receive some kind of harbor from incidents that occur despite following the proper procedures.

Health care organizations also should demonstrate that they are eager to hear from users about ways that the system could be improved. They should have explicit ways for users to report problems, to understand the status of problems that have been reported, and to know whether others have reported similar problems, and to know the status of the problem they have reported. Best practices dictate that reporters should be notified when a problem has been addressed. Only with this full feedback loop will the reporting of problems be encouraged. At organizations where this loop in not closed, users are not incented to report future problems because they do not think they will get an answer.